



AUG -2 2004

David Mase
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Wallingford CT 06492In Re: Patent Term Extension
Application for
U.S. Patent No. 4,980,470

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,980,470, which claims the human drug product TEQUIN® (gatifloxacin), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 721 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 721 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 26, 2003 (68 Fed. Reg. 14665). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (732) + 355 \\ &= 721 \text{ days}\end{aligned}$$

Since the regulatory review period began December 27, 1996, after the patent issued (December 25, 1990), the entire period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,980,470
Granted:	December 25, 1990
Original Expiration Date ¹ :	December 25, 2007
Applicant:	Kuniyoshi Masuzawa, et al.
Owner of Record:	Kyorin Pharmaceutical Co., Ltd.

¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: 8-ALKOXYQUINOLONECARBOXYLIC ACID
AND SALTS THEREOF

Classification: 544/363

Product Trade Name: TEQUIN

Term Extended: 721 days


Expiration Date: December 15, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: TEQUIN®
FDA Docket No. 01E-0030